# PBAC CONSIDERATION OF THE REPORT OF THE DRUG UTILISATION SUB-COMMITTEE

The PBAC noted utilisation reports with associated stakeholder responses from the June 2015 Drug Utilisation Sub-Committee (DUSC) meeting, which were provided in items 10.03 to 10.07 of the PBAC Agenda. Minutes for these items were tabled. The June 2015 DUSC Outcome Statement is available from: http://www.pbs.gov.au/info/industry/listing/elements/dusc-meetings/dos/

## Medicines used in the management of attention deficit hyperactivity disorder

The PBAC noted the increasing use of attention deficit hyperactivity disorder (ADHD) medicines. The PBAC noted that the current version of the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5) tool, which is used to assess eligibility for treatment for ADHD, has a lower threshold to diagnose ADHD compared to the prior version. The PBAC considered that the progression of adolescent patients to adult age is a factor in the rise in the number of adults receiving ADHD medications.

The PBAC noted that long acting methylphenidate has had the greatest use. The PBAC noted that while atomoxetine had the lowest utilisation, expenditure on this agent has been high relative to the other PBS listings.

The PBAC noted that the median length of treatment on ADHD medicine was 4.2 years. The PBAC noted that there is no clear guidance on duration of use but considered that treatment breaks are used in practice to assess if there is a need for continued therapy.

The PBAC was concerned that children aged 5 years and younger were receiving an antipsychotic. The PBAC considered that the practice of using antipsychotics for behaviour modification in this patient group was inappropriate.

The PBAC noted that a relatively high proportion of patients prescribed an ADHD medicine were also prescribed an antidepressant. This was highest for adults, with at least one in four adults dispensed an ADHD medicine also receiving an antidepressant.

The PBAC noted that the majority of prescriptions are written by a specialist, usually a paediatrician or psychiatrist. Most Australian states and territories restrict the prescribing of methylphenidate and dexamphetamine for the treatment of ADHD to specialist medical prescribers. The PBAC noted the differing rates of use of ADHD medicine across the states and territories, in particular the higher rate of prescribing of ADHD medicines to adults in Western Australia. The PBAC noted that the Australian Commission on Safety and Quality in HealthCare (ACSQHC) is developing an Australian Atlas of Healthcare Variation that aims to identify and reduce unwarranted healthcare variation and to improve patient care and outcomes, while ensuring value in healthcare spending. The Atlas is due for release in late 2015. The PBAC considered that this resource will provide further insight into prescribing variation.

The PBAC considered that there is an opportunity to improve prescribing of ADHD medicines. The PBAC requested that the DUSC report be provided to the relevant professional colleges and to NPS MedicineWise to support initiatives to improve quality use of ADHD medicines.

## Medicines used for age related macular degeneration

The PBAC noted that the number of patients treated with ranibizumab or aflibercept for wet AMD has been steadily increasing over recent years, with 36,730 patients treated in 2014. The PBAC agreed with the DUSC that the utilisation of aflibercept and ranibizumab for wet AMD will continue to increase into the future due to an ageing population and high rates of continuation on treatment.

The PBAC noted that there was a rapid uptake of aflibercept within its first 6 months of listing, capturing around half the market within that time. The PBAC noted that aflibercept was used in new patients and those who had switched from ranibizumab.

The PBAC recalled that when recommending the listing of aflibercept that there was a high degree of uncertainty regarding the number of injections that would be administered in clinical practice, and recommended listing on an injection: injection basis with ranibizumab. In considering the findings of the DUSC review and noting the ongoing evolution of clinical practice, the PBAC agreed with its DUSC that further observational data would be needed to verify if the numerical differences seen in the number of injections for the initiating cohort examined in the review would persist in the longer term.

## Dutasteride and dutasteride with tamsulosin for benign prostatic hyperplasia

The PBAC noted that the utilisation of dutasteride and dutasteride with tamsulosin had been below predicted levels. The PBAC considered that there may have been an overestimate of unmet need at the time of recommending listing.

The PBAC considered that the requirement for treatment to be initiated by a urologist may also be a factor in the lower than expected use of these agents. The PBAC recalled that the restriction requested in the November 2009 resubmission for dutasteride included initiation by a urologist, which the PBAC considered appropriate, noting that mild BPH patients were removed from the baseline in the economic model on the basis that it is unlikely that urologists would be treating mild BPH with the combination of dutasteride and an alpha-antagonist.

The PBAC noted that gaining access to a urologist would be difficult for some patients.

The PBAC noted that other factors which may account for the lower than expected use may include: an overestimate of the eligible population and the willingness of patients to seek treatment; an unwillingness of patients to persist with treatment from a lack of understanding that the benefits may not be experienced for some time after commencing therapy; and adverse events.

The PBAC noted that advice had been sought from the Urological Society of Australia and New Zealand (USANZ) regarding the impact of removing the requirement for urologist initiation. The PBAC requested that advice also be sought from general practitioners, particularly regarding barriers to accessing specialist services and management of BPH at the primary care level. The PBAC deferred further consideration of this item pending the advice from these groups.

## Icatibant for hereditary angioedema

The PBAC noted that the actual utilisation of icatibant in terms of patient numbers and prescriptions had been substantially lower than predicted, however the use per patient was higher than anticipated.

The PBAC considered that the higher use seen in the review may be appropriate because of changes in the treatment algorithm. However, this change in practice may no longer be cost-effective as established under the original economic modelling and assumptions at the time of icatibant’s initial listing.

The PBAC considered that a major submission would be required to assess the cost-effectiveness of icatibant in the context of an updated treatment algorithm and to support any proposed change in the PBS restriction. The PBAC noted that the restriction recommends the use of icatibant in accordance with the Australasian Society of Clinical Immunology and Allergy (ASCIA) Action Plan for Hereditary Angioedemia (HAE). The PBAC considered that a revised economic model reflecting current clinical practice, including any revisions to the ASCIA Plan, and the presentation of new evidence of any additional benefits, such as improvements in quality of life or potential offsets from hospital use, would be informative.

## Romiplostim and eltrombopag for idiopathic thrombocytopenic purpura

The PBAC noted that the number of initiating patients was overestimated for the first year of listing but there were higher than than expected rates of patient initiation in the second and third listing years. The PBAC noted that there was less continuation on thrombopoietin receptor agonist (TRA) therapy in the longer term than estimated. The PBAC considered that the restriction, which allows patients to stop and then restart treatment without needing to requalify, facilitates the appropriate use of these medicines.

PBS subsidised TRA therapy is available for failed splenectomy and for patients who are medically unfit for splenectomy. The PBAC noted that there was an increasing trend in the proportion of non-splenectomised patients accessing TRA therapy. The use of TRA therapy as an alternative to splenectomy has not been presented to the PBAC to assess the cost-effectiveness of this. The PBAC agreed with its DUSC that it would be appropriate to establish further criteria to assess the suitability for splenectomy and requested that advice be sought from relevant clinicians, sponsors and stakeholders. The inclusion of specific criteria and tick boxes may reduce the burden on prescribers and Medicare Australia staff during the written authority process.

The PBAC noted a joint request from the Australasian Society of Thrombosis and Haemostasis (ASTH) and the Haematology Society of Australia and New Zealand (HSANZ) to allow continuation of TRAs in a sub population of patients who have a significant clinical response but who do not qualify for ongoing PBS supply based on platelet count alone. The PBAC noted that no data was provided on the size of this clinical population and therefore the budget impact of this request could not be assessed. A formal submission including these necessary details would be welcomed.

The PBAC considered that examining the use of TRAs by non-splenectomised patients by age as part of future reviews could be informative as surgery may be contraindicated in patients of advancing age. Also analysis of any additional data collected about why splenectomy was contraindicated using the current forms, or via revised forms with tick boxes, will be highly informative.